

AUG 19 2004

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PREMARKET NOTIFICATION 510(K) SUMMARY

Sponsor: HMT High Medical Technologies AG
Kreuzlingerstrasse 5
CH-8574 Lengwil
Switzerland
Telephone: 011.41.71.686.6200
Fax: 011.41.71.686.6209
Contact: Karl Ensslen, PhD

Manufacturer: HMT High Medical Technologies AG
Kreuzlingerstrasse 5
CH-8574 Lengwil
Switzerland
Telephone: 011.41.71.686.6200
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Contact: Karl Ensslen, PhD

Establishment Registration Number: 9614425

Contact Person: Patricia Landry
M Squared Associates, Inc.
719 A Street, NE
Washington DC 20002
Telephone: 202-546-1262
Fax: 202-546-3848
E-mail: tlandry@msquaredassociates.com

Trade Name of Device: Ultrasound Localization System ULS 0142
Common Name: Accessory to Extracorporeal Shock Wave Lithotripter
Classification name: Lithotripter, Extracorporeal Shock-Wave, Urological
Product Code: LNS
Regulation Class: Class II (Special Controls)

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Regulation Number: §876.5990

Device Description: The ULS0142 accessory is an adjunct ultrasound localization system for use prior to extracorporeal shock wave lithotripsy with the LithoDiamond LTFS230.

The ULS0142 is not indicated for use as a stand-alone diagnostic ultrasound system, and should only be used for lithotripsy-related applications.

Indications for Use: The ULS 0142 accessory is indicated for ultrasound localization of a target stone prior to extracorporeal shock wave lithotripsy with the LithoDiamond LTFS230.

The ULS0142 is not indicated for use as a stand-alone diagnostic ultrasound system, and should only be used for lithotripsy-related applications.

Basis for Substantial Equivalence The LithoDiamond ULS 0142 is substantially equivalent to the LithoTron ULS 0132.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2004

HMT High Medical Technologies AG
c/o Ms. Trish Landry
Senior Consultant
M Squared Associates, Inc.
719 A Street, N.E.
WASHINGTON DC 20002

Re: K040741

Trade/Device Name: HMT Ultrasound Localization System ULS 0142
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: August 6, 2004
Received: August 6, 2004

Dear Ms. Landry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K040741Device Name: Ultrasound Localization System ULS 0142

Indications For Use: The ULS0142 accessory is indicated for localization of a target stone prior to extracorporeal shock wave lithotripsy with the LithoDiamond LTFS230.

The ULS0142 is not indicated for use as a stand-alone diagnostic ultrasound system, and should only be used for lithotripsy-related applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

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